

REMARKS/ARGUMENTS

Claims 1, 3 and 5-15 and 22-23 are active. Claims 16-21 have been withdrawn from consideration. The Applicants thank Examiners Young and SPE Wilson for the courteous interview of April 11, 2003. The claims have previously been limited to β 1,3-1,6 glucan produced by a single deposited strain (FERM P18099) of *Aureobasidium* fungi. The Examiners were concerned that the prior art fungal strains may produce *exactly* the same type of glucans that strain FERM P18099 does, and thus have maintained the prior anticipation rejections. It was suggested that the Applicants further elaborate on how the β 1,3-1,6 glucan produced by strain FERM P18099 differs from glucans produced by other types of fungi, especially other *Aureobasidium* fungi. The Applicants do maintain the Office has the initial burden of asserting a reason why it believes that all different strains of *Aureobasidium* would make exactly the same type of β 1,3-1,6 glucan, to expedite prosecution Applicants now show how the β 1, 3-1, 5 glucan produced by strain FERM P18099 would differ from glucans produced by other fungi, especially from those of other strains of *Aureobasidium* fungi. Favorable consideration is respectfully requested.

Election/Restriction

The Applicants note that the prior restriction requirement has now been made final. Upon an indication of allowable subject matter, they respectfully request rejoinder of nonelected method claims which depend from or which otherwise include all the limitations of an allowable product claim.

Anticipation Rejections

All the following prior art rejections are based on documents which disclose glucans produced by fungal strains which are not the particular deposited strain recited by the claims: FERM P18099. The Patent Office position is that the prior art inherently discloses the same β 1,3-1,6 glucan absent evidence to the contrary. However, none of the cited prior art explicitly discloses that the β 1,3-1,6 glucan produced by strain FERM P18099 is the same as any of the glucans produced by the prior art fungi.

Prior to review of the responses to the prior art rejections, the Applicants direct the Examiner's attention to MPEP 2131.02 and the following case law citation:

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA v. Monsanto Co., 20 USPQ2d 1746 (Fed. Cir. 1991).

In the present case, the Applicants have limited all the claims to β 1,3-1,6 glucan produced by a deposited strain FERM 18099 and assert that one with ordinary skill in the art would not expect that every strain of *Aureobasidium* makes the exactly the same type of beta-glucan. The Office has not presented any extrinsic evidence to indicate that all strains of *Aureobasidium*, or even that all strains of *Aureobasidium pullulans*, necessarily produce the same type of β 1,3-1,6 glucan.

Moreover, the β 1,3-1,6 glucan compositions produced by FERM P18099 of the present invention have functional properties which distinguish them from similar compositions produced by other similar fungal strains, e.g., strain FERM P4257. These properties include a stronger ability to induce DNA synthesis, induce cytokine synthesis, such as IL-8 production, and differentially influence the antigenic characteristics of cell surface

antigens compared to strain FERM P4257. Therefore, the Applicants respectfully request that the anticipation and obviousness rejections below be withdrawn.

Rejection – 35 U.S.C. § 102

Claims 1, 3, and 5-7 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hamada, Agric. Biol. Chem. 47(6): 1167-1172. The present claims are limited to β 1,3-1,6 glucans from strain FERM P18099. Page 8 of the specification indicates that strain FERM P-18099 is a kind of *Aureobasidium pullulans*.

Hamada, page 1167, first col., lines 10-12, indicates that the polysaccharide produced by the *Aureobasidium* strain of Hamada “differed from those produced by *Aureobasidium pullulans*”.

Since the Hamada polysaccharides differ from those produced by *Aureobasidium pullulans*, they differ from those of the present invention. Accordingly, this rejection may now be withdrawn.

Rejection – 35 U.S.C. § 102

Claims 1, 3, 5, 6, and 8-12 were rejected under 35 U.S.C. § 102(b) as being anticipated by patent publication JP 06-340701 A to Watanabe et al. This document teaches beta-glucan from *A. pullulans* strain IFO 4466. While the Watanabe beta-glucan is disclosed as having particular structural characteristics, Watanabe does not disclose or suggest a glucan produced by strain FERM P-18099, the strain to which the present claims are limited.

Rejection – 35 U.S.C. § 102(b)

Claims 1, 3, 5, 6, 8 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by patent publication JP 62-205008 A to Shinohara et al. Shinohara discloses a β 1,3-1,6 glucan produced by *Aureobacidium* sp. The specific species of *Aureobasidium* is not described, nor is there any disclosure of strain FERM P18099. There is no reasonable basis for believing that the Sinohara *Aurobasidium* sp. is strain FERM P18099, nor believing that it produces the same type of β 1,3-1,6 glucan as strain FERM P18099. Accordingly, the Applicants submit that this rejection should be withdrawn in view of the amendment of the claims to glucans produced by strain FERM P18099.

Rejection – 35 U.S.C. § 102(b)

Claims 1, 3, 5, 6, 8 and 14-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by patent publication JP 06-146036 A to Hasegawa et al. This English Abstract discloses a β 1,3 glucan from *Auerovacidium*. It does not disclose β 1,3-1,6 glucan from *Aureobasidium pullulans* strain FERM P18099. There is no reasonable basis for believing that the Hasegawa β 1,3 glucan is a β 1,3-1,6 glucan or that it is produced and has the characteristics of that produced by strain FERM P18099. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection – 35 U.S.C. § 103(a)

Claims 1-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over patent publication JP 06-340701 A to Watanabe et al., in view of Finkelman et al., Canadian Journal of Microbiology, 33(2): 123-127.

The Applicants submit that this rejection may be withdrawn in view of the amendment of the claims to specify that the glucan is produced by strain FERM B18099.

This strain is disclosed nor suggested by the cited prior art. The Official Action asserts that it would have been obvious to use any strain of *Aureobasidium*, including strain FERM P-18099, to make β -1.3-1.6-glucans.

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, see MPEP 2144.06 (col. 2, on page 2100-139, Feb. 2003 edition). However, the documents cited by the outstanding rejection do not establish that strain FERM P-18099 is recognized in the prior art as an equivalent to other *Aureobasidium* strains.

Moreover, as apparent from page 1167, col. 1, of the Hamada reference (mentioned above), not all *Aureobasidium* strains produce equivalent carbohydrates. The characteristics of strain FERM P-18099 are extensively described in the disclosure starting at page 7, line 21. However, a strain with these same characteristics is not described by the cited documents. As there is no description of strain FERM P-18099 in the cited prior art, nor adequate description in the cited prior art that this strain is equivalent to prior art strains, the Applicants respectfully submit that this rejection be withdrawn.

Rejection – 35 U.S.C. § 103(a)

Claims 22-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over patent publication JP 06-340701 A to Watanabe et al. Claims 22 and 23 both require a product comprising the β -1.3-1.6-glucan from FERM P-18099. Watanabe does not render obvious the product of Claim 22, because this document does not disclose or suggest 1.3-1.6-glucan from FERM P-18099, only a highly branch beta-glucan from a different *A. pullulans* strain IFO 4466. Moreover, Claim 22 requires a product formulated as a disinfectant or sanitizer from such a glucan. Wantanabe (English Abstract) does not disclose or suggest

Application No. 09/986,535
Reply to Office Action of October 16, 2003

sanitizers or disinfectants formulated from such glucans. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully submit that this application is now in condition for allowance. Early notification to this effect is earnestly solicited.

Respectfully submitted,

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